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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,099	09/17/2003	Jennifer Maw	PD-267.00 (M190.151.101)	3704
42035	7590	10/14/2008	EXAMINER	
ALTIMATIA, L.L.C.				
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			ART UNIT	PAPER NUMBER
			3731	
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			10/14/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/664,099

**Applicant(s)**

MAW, JENNIFER

**Examiner**

TUAN V. NGUYEN

**Art Unit**

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 9-14, 16, 17 and 20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-14, 16, 17 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on January 9, 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. In previous Office action Claims 1-5, 9-14, 16, 17, and 20 are pending in this present application and these claims were examined and rejected.

***Response to Amendment***

2. Applicant's arguments filed on July 10, 2008 have been fully considered but they are moot in view of the new grounds of rejection.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-5, 9-14, 16, 17, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1, new limitation "A sterile" recited in preamble is new matter. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 1, 3-5, 16-17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seager et al (US 4,744,494) in view of Kroll et al. (U.S. 6,592,513) and further in view of Elliott (US 5,908,404).**

8. Referring to claims 1, 3-5 and 16-17, Seager discloses (see Figs. 1-6 and col. 3, line 5 to col. 5, line 55) a system for delivering or dispensing viscous fluid materials and adhesive (see Background of The Invention), thus the system is capable of deliver or dispense adhesive to an ear, comprising: a housing 2 (see Fig. 1) or a cylindrical housing 102 (see Fig. 6); a handle 12, 112 having a terminus; a trigger 16, 116 pivotally connected to handle through a hinge 18, 118, which allows the trigger to pivot about the joint when the trigger is squeezed; a cartridge 43, which contained entirely within the housing 2, 102 (see Fig. 4); a dispensing mechanism

operatively connected at one end to the trigger and at the other end to the reservoir; the dispensing mechanism includes ram 30, 130 having racks 32, 32a or teeth engaged with pawl 28, 128 mounted on the trigger 16, 116 and plunger tip 46 (see Fig. 4), wherein the outer diameter of plunger tip is approximately equal to the inner diameter of the cartridge 43(see Fig. 4); a tip 8 or cannula fluidly connected to the second end of the cartridge (see Figs. 1 and 4). Referring to **claim 10**, Seager discloses (see Figs. 1 and 4) the tip 50 is permanently affixed to the cartridge. Seager discloses the invention substantially as claimed except for specifically disclose that the adhesive is a sterile adhesive for an otology procedure.

9. However, Kroll discloses a method for creating a coupling between an implantable device, such as a transducer, and the structure of the ear, such as an ossicle by using otologic adhesive such as cyanoacrylate, fibrin glue or other surgical adhesive because the formation of a bond at the ossicle/adhesive interface does not inhibit the natural motion of the ossicle (see Abstract; col. 4, lines 7-10; and col. 7, lines 21-45). Therefore, it would have been obvious to one of ordinary skill in the art to further utilize the device of Seager into the field of medical device by using the device of Seager to dispensing the otologic adhesive as suggested by Kroll. Further, it is old and well known in the art that the Food and Drug Administration requires all implants must be sterile at the time of use because a non-sterile implantable device may have severe consequences for the patient such as serious infection. Therefore, it would have been obvious to one of ordinary

skill in the art to sterile the adhesive before it is being implanted into a patient to prevent serious infection. Extrinsic evidence, US Patent No. 5,908,404, column 5, lines 12-20.

10. Referring to **claim 20**, the modified device of Seager discloses the invention substantially as claimed except for the ratchet mechanism capable of delivery a dosage as small as 5-10 microliter. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Extrinsic evidence, Epstein (U.S. 5,226,877) discloses that a ratchet mechanism for dispensing fibrinogen adhesive with such accuracy as claimed by the applicant (see col. 14, lines 35-48).
11. **Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seager et al in view of Kroll and Elliott as applied to claim 1 above and further in view of Brown et al (U.S. 5,201,752).**
12. The modified device of Seager discloses the invention substantially as claimed except for the handle comprise a ring to allow a finger or a thumb to be placed in the ring. However, Brown discloses such a feature. Brown discloses a cholecystectomy dissector instrument comprising, among other things: a handle with ring to allow a finger or a thumb to be placed in the ring thereby providing an ergonomically superior scissors action handle for the surgeon to better control and feel during handling the instrument (see Abstract and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art to modified the handle of

Seager device according to the teaching of Brown so that it to would have the same advantage.

13. **Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seager et al in view of Kroll and Elliott as applied to claim 1 above and further in view of Wyrick (U.S. 5,695,472).**
14. The modified device of Seager discloses the invention substantially as claimed except for the reservoir is transparent. However, Wyrick discloses (see Fig. 1) a medicine injection system comprising, among other things: barrel 16 and syringe subassembly 24 has a medicament cartridge 26 which includes and ampule wherein the barrel and ampule are preferably constructed of transparent material to allow the user to view into the injector to determine whether there is a cartridge in the injector and to determine whether the medicine in the ampule has become unsuitable for injection (see col. 3, lines 43-60 and col. 10, lines 45-53). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the teaching of Wyrick into the device of Seager so that it too would have the same advantage.
15. **Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seager et al in view of Kroll and Elliott as applied to claim 1 above and further in view of Dragan (U.S. 4,472,141).**
16. The modified device of Seager discloses the invention substantially as claimed except for the cannula is removable and fluidly connected to the reservoir and the cannula having a specific gauge. However, Dragan discloses a system for

delivering or dispensing a variety of different dental materials in dentistry and certain surgical procedure, comprising, among other things: a cannula is removable and fluidly connected to the reservoir (see Abstract and col. 7, lines 9-50). Therefore, it would have been obvious to one of ordinary skill in the art to modified Seager device as suggested by Dragan for the purpose of having a capability of receiving a plurality of needle gauges to dispense a variety materials. With respect to **claims 13-14**, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Extrinsic evidence, Silverman discloses an apparatus and method of injecting a nonbiodegradable such as cyanoacrylate, which is a non-toxic chemical inert prepolymer for in situ (see col. 11, line 48-59) through a needle having a gauge size ranging from 16 to 28 preferably ranging from 23 to 26 gauge (see col. 4, lines 15-23)

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within



TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./

Examiner, Art Unit 3731

Art Unit: 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731